

WHOLESALE & OTHER DRUG DISTRIBUTORS AND 503b OUTSOURCING FACILITIES NEW APPLICATION INSTRUCTIONS

General Information

- License renewal period is November 1-December 31 each year.
- All licenses will expire December 31 each year. There is no grace period.
- For current South Dakota Statutes and Rules, go to <https://doh.sd.gov/boards/pharmacy/>, under Quick Links are law book link options.
- License fee is \$250 for all licenses except 503b is \$200.
- Payment methods – Mastercard or Visa **ONLY**.
- User ID and password must be unique for each licensed facility once license is approved/issued.

You must complete the entire application process from start to finish in one sitting

- Online system does not retain any information entered until the application has been submitted and payment process is complete.
- Have all of your information and copies of documents for upload ready before beginning the online application process.

Required Documents to be Uploaded

- Current home state license, its equivalent, or a written explanation why one is not available. (A primary source verification does not fulfill this requirement).
- Most recent home state, FDA, or VAWD inspection conducted within the last 4 years for this facility if home state is not SD. Explain if not available. Include deficiency correction documentation. 503b must provide an FDA inspection.
- Copy of Federal DEA certificate if dispensing controlled substances.
- If 503B Outsourcing Facility, FDA inspection report and deficiency correction documentation are required.
- If Virtual Manufacturer, provide:
 - 3PL name(s), address(es), and copy of agreement(s) first page and signature page only.
 - Contract Manufacturer name(s), address(es), and copy of agreement(s) first page and signature page only.
 - Product/NDC List
- If Virtual Distributor, provide:
 - 3PL name(s), address(es), and copy of agreement(s) first page and signature page only.
- A **list** of other state(s) entity is licensed in.
- Owner or Corporate Officer Certification, form can be found at <http://doh.sd.gov/boards/pharmacy/wholesalers.aspx>

After Application Submission Information

After your application has been submitted, the Board will:

- Review the application
- Email licensing contact if additional information is needed
- Approve or deny the application

Once the new license is approved/issued, a profile account will need to be set up.

- Instructions to set up a profile account are at the end of this manual (beginning on page 10)
- For the profile account, a unique User ID and password for *each* licensed pharmacy will need to be established.
- Retain User ID/password to have ability to access the licensing platform when needed.

After the license is approved/issued and the profile account is set up, you will be able to do the following:

- To check application status
- Print facility license (instructions on page 12)
- Print a payment receipt (instructions on page 12)

Licensure status can also be verified at:

- Verification page: <http://doh.sd.gov/boards/pharmacy/verification.aspx>

Application for New Wholesaler & Other Drug Distributors and 503b Outsourcing Facilities Pharmacy User Manual

Instructions:

1. Click on the link below for initiating a new Wholesaler & Other Drug Distributors and 503b Outsourcing Facilities Pharmacy License. **Please Bookmark this page.**
<https://sdbop.igovsolution.com/initial/initial/initial.aspx?id=72>
2. Below page will open with instructions:

WHOLESALE & OTHER DRUG DISTRIBUTORS INSTRUCTIONS

General Information

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- All licenses will expire December 31 each year. There is no grace period.
- For current Statutes and Rules, go to <https://doh.sd.gov/boards/pharmacy/>, under Quick Links are law book link options.
- License fee is \$250 for all licenses except 503b is \$200.
- Payment methods – Mastercard or Visa ONLY.
- User ID and password must be unique for each license.

You must complete the entire renewal application process from start to finish in one sitting

- Online system does not retain any information entered until the application has been submitted and payment process is complete.
- Have all of your renewal information and copies of documents for upload ready before beginning the online renewal process.

Required Documents to be Uploaded

- Current home state license, its equivalent, or a written explanation why one is not available. (A primary source verification does not fulfill this requirement).
- Most recent home state, FDA, or VAWD inspection conducted within the last 4 years for this facility if home state is not SD. Explain if not available. Include deficiency correction documentation. 503b must provide a FDA inspection.
- Copy of Federal DEA certificate if dispensing controlled substances.
- If 503B Outsourcing Facility, FDA inspection report and deficiency correction documentation are required.
- If Virtual Manufacturer, provide:
 - 3PL name(s), address(es), and copy of agreement(s) first page and signature page only.
 - Contract Manufacturer name(s), address(es), and copy of agreement(s) first page and signature page only.
 - Product/NDC List
- If Virtual Distributor, provide:
 - 3PL name(s), address(es), and copy of agreement(s) first page and signature page only.
- List of other states licensed in.
- Add Owner or Corporate Officer Certification, form can be found at <http://doh.sd.gov/boards/pharmacy/wholesalers.aspx>

After Application Submission Information

After your application has been submitted, the Board will:

- Review the application
- Email licensing contact if additional information is needed
- Approve or deny the application

You must log back into the account at https://sdbop.igovsolution.com/online/User_login.aspx

- To check application status
- Print license
- Print a receipt

Application status can also be done at

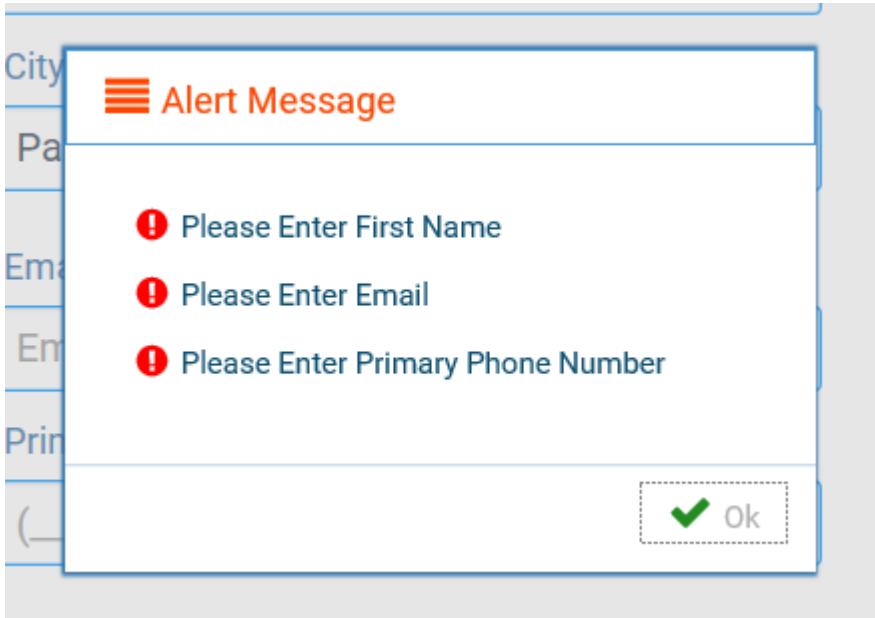
- Verification page: <http://doh.sd.gov/boards/pharmacy/verification.aspx>

Be sure to read all the instructions on this screen and click on any links provided on the page for more information. Then click on Next button to continue.

General Note

1) Mandatory fields are marked with a red * in all screens and all those have to be entered before clicking on next

2) If mandatory fields are not entered, you will get an alert message that alerts to enter those fields like below:



The image shows a screenshot of a web application with a modal dialog box titled "Alert Message". The dialog box has a blue border and a white background. It contains three error messages, each preceded by a red exclamation mark icon: "Please Enter First Name", "Please Enter Email", and "Please Enter Primary Phone Number". At the bottom right of the dialog box, there is a button with a green checkmark icon and the text "Ok". In the background, parts of form fields are visible, including labels for "City", "Pa", "Em", "En", "Prim", and a parenthesis "(".

3. Complete application:

- Click on Next button to begin the application.

WHOLESALE & OTHER DRUG DISTRIBUTORS INFORMATION

Wholesale & Other Drug Distributors Information

* Legal Name of Business

DBA Name, if applicable

* Address1

Address2

Address3

* Zip

* City

* State

* County

* Responsible Person at Firm

* Responsible Person Title

* Email

* Phone Number

Fax Number

Legal name of Parent Company Headquarters/Corporate Office

* Name

* Address 1

Address2

Address3

* Zip

* City

* State

* County

* Legal Phone

Legal Fax

License Preparer Information

☐ Same as Wholesale & Other Drug Distributors Information Provided

* Contact Name

* Contact Title

* Company Name

* Address1

Address2

Address3

* Zip

* City

* State

* County

* Email

* Phone

Fax

* Type of Distribution (check all that apply)

☐ Wholesale Distributor ☐ Manufacturing Distributor ☐ Repackager ☐ Distribution Center

☐ Reverse Distributor ☐ Virtual Manufacturing ☐ Virtual Distributor ☐ In State Only - Third Party Logistics Provider

☐ 503B Outsourcing Facility ☐ Other

* Type of Prescription Drugs/Products (check all that apply)

☐ Medical Gases ☐ DEA Controlled substances ☐ Ephedrine or pseudoephedrine products ☐ Noncontrolled prescription drugs ('federal legend')

☐ Over-the-Counter drugs ☐ Veterinary prescription drugs ☐ Other

Types of Customers you sell/distribute to (check all that apply)

☐ Other Wholesalers ☐ Hospitals ☐ Pharmacies ☐ Practitioners/Clinics ☐ Patients ☐ Other

- Enter all the required information (marked with red *)
- Select the Type of Distribution, Type of Prescription drugs/products, Types of customers you sell/distribute to.
 - Note: you can select all that apply if you have more than one type.
 - Note: if you want to add 3PL, Contract Manufacturer information then select the Virtual Manufacturing and/or Virtual Distributor under Type of Distribution and use the click here to add more button.
 - Also, please note if your country is Outside USA then first select the country and then it will allow to enter the Zip code as alpha numeric and you can select the State as Outside USA from the drop-down list.

*** Type of Distribution (check all that apply)**

☐ Wholesale Distributor
 ☐ Manufacturing Distributor
 ☒ Repackager
 ☐ Distribution Center
☐ Reverse Distributor
 ☒ Virtual Manufacturing
 ☐ Virtual Distributor
 ☐ In State Only - Third Party Logistics Provider
☐ 503B Outsourcing Facility
 ☐ Other

Click Here To Add For 3PL Details [Click Here To Add More](#)

Click Here To Add More For Contract Manufacturer [Click Here To Add More](#)

3PL Details

* Name of Business:

* Address1: Address2:

Address3: Address2:

* Zip: * City:

* State: * Country:

Select State: United States:

Copy of 3PL agreement, first page, along with signature page [Attach Document](#)

3PL VAWD accreditation upload [Attach Document](#)

[Save](#) [Cancel](#)

IN
KS
KY
LA
MA
MD
ME
MI
MN
MO
MS
MT
NC
ND
NE
NH
NJ
NM
NV
NY
OH
OK
OR
Outside USA

3PL Details

* Name of Business:

* Address1:

Address3: * Zip:

Address3: * City:

* State: * Country:

Outside USA: United Kingdom:

Copy of 3PL agreement, first page, along with signature page

3PL VAWD accreditation upload

[Save](#) [Cancel](#)

- Click on Next button

Ownership:

- Select the type of Ownership
- Based on the selection you will see the different options to add and/or upload the necessary information
- If you would like to add more than one ownership type, (Example: adding 2 or 3 different ownership names under LLC), then use the Click here button to add more details

OWNERSHIP

*** Type of Ownership**

☐ Sole Proprietorship
 ☐ Partnership
 ☐ Corporation
 ☒ LLC
 ☐ Other

Name and Address of LLC [Click Here](#)

1	Name Of LLC : LLC1	Address1 : A1	Address2 :	Address3 :	Zip : 70091	City : Venice	State : LA	Phone Number : (222) 222-2222	Delete
2	Name Of LLC : LLC2	Address1 : A2	Address2 :	Address3 :	Zip : 22101	City : Mc Lean	State : VA	Phone Number : (222) 222-2222	Delete

Partner/member/officer information [Attach Document](#)

Is pharmacist-in-charge sole owner of merchandise and fixtures? ☐ Yes ☐ No

[Previous](#) [Next](#)

- Attach the supporting partner/member/officer document(s)
- Click Next

Registered Agent in SD:

- Enter the details of the Registered agent in the state of South Dakota in this screen. **Note:** To view a list of the SD registered agents, click on that link at the bottom of the screen.

REGISTERED AGENT IN SD

* Name <input type="text"/>	* Address1 <input type="text"/>	Address2 <input type="text"/>
Address3 <input type="text"/>	* Zip <input type="text"/>	* City <input type="text"/>
* State <input type="text" value="Select State"/>	* County <input type="text" value="Select County"/>	

For a list of SD registered agents go to https://sdsos.gov/docs/business/CRA_list.pdf

- Click Next

Home State license / Inspection:

Note: This section/screen will appear only if the Wholesaler license information address in the 1st screen is Outside SD

HOME STATE LICENSE/INSPECTION

Home State License
Do you hold a home state license or its equivalent? ☐ Yes ☐ No

Copy of the licensee's DEA

Home State License

Home State or Other Inspection
* Type of Inspection: * Date of last inspection:

Upload last inspection or a document stating reason for no inspection

Were there any deficiencies in the inspection identified above? ☐ Yes ☐ No

VAWD
VAWD Accredited? ☐ Yes ☐ No

States Licensed In
Provide a List of All States Licensed in (Use comma to type out multiple states). Please note that there is an option to upload the list of states in the Attachments section at the end. If you prefer to do that, please type 'See Attached' in the box below.
* List other states licensed in ☐ See Attached

- Answer the question if you hold a home state license or its equivalent – Yes / No
 - If you answered Yes, then enter the Home state, Home State license number, License expiration date.
 - And if answer is No, then enter the explanation and attach the document
- Attach the Mandatory documents: DEA certificate, Home state license
- Select the appropriate Home state inspection, if answer is No inspection then make sure to attach/ upload a document stating the reason for no inspection.
- Answer the other Inspection question
- Select the VAWD accredited, if applicable

- If licensed in other states, either enter the names of the states like AZ, MN, SD, IA etc. on the List other states licensed in box **or** select the checkbox see attached and attach the document with a list of all the states where you are licensed
- Click Next


Owner Certification:

- Upload the Owner or Corporate Officer certification form

OWNER CERTIFICATION

Attachments – upload to this section the mandatory document, 'Owner or Corporate Officer Certificate Form'. The Owner or Corporate Officer Certification Form must be signed with original ink or an e-signature will be accepted that is similar to E-Signature by Adobe Sign. If a power of attorney is being used, the power of attorney documents must be uploaded with the Owner or Corporate Officer Certificate Form.

Owner or Corporate Officer Certification Form



- Click Next


Disciplinary questions:

- Answer the Regulatory questions and if answered Yes, explanation(s) **must** be added and **must** upload the supporting document(s).

DISCIPLINARY ACTION

Have any misdemeanor or felony convictions or disciplinary actions (including pending) been taken against the applicant and/or licensed entity in the last 7 years? ☒ Yes ☐ No

* Explanation



- Click Next

Application Preview page:

- Review the application in this screen before moving to the Payment page. After completing the application, you will be able to review the application for any errors and correct the information by clicking on Previous buttons and correct in the appropriate screens.
- Use the vertical scroll bar to scroll it down to view.

APPLICATION INPUT PREVIEW

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- If 503B Outsourcing Facility, FDA inspection report and deficiency correction documentation are required.
- If Virtual Manufacturer, provide:

Previous
Next

Affirm and Submit Page:

- Check the box as shown below
- Fill the E-signature, select the Debit or Credit card, enter the card type (Visa, MasterCard **ONLY**), enter the card number, Expiration date, Security code (the 3 digits CVV code on your credit card) and click Submit

AFFIRM AND SUBMIT

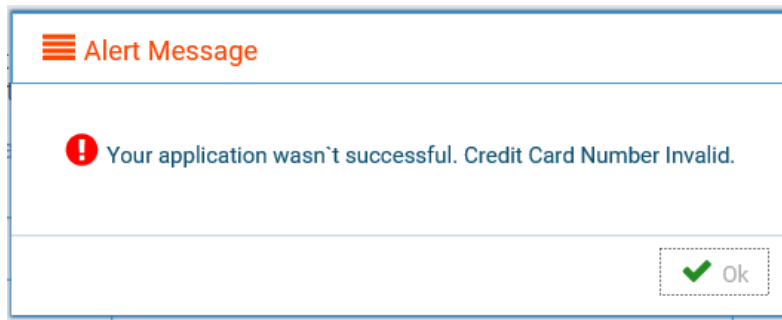
☐ I certify that the applicant will operate in a manner prescribed by federal and state laws and rules adopted by the Board. I declare and affirm under the penalty of perjury that this application has been examined by me, and to the best of my knowledge and belief, is in all things true and correct.

<p>* E-Signature of the person filling out this renewal</p> <p>Type in full name</p>	<p>* Date</p> <p>05/14/2019</p>	<p>License Fee</p> <p>\$250.00</p>
<p>* Select Debit or Credit</p> <p>Select</p>	<p>* Card Type</p> <p>Select Card Type</p>	<p>* Person's Name on Card</p> <p>Person's Name on Card</p>
<p>* Card #</p> <p>Card #</p>	<p>* Expiration Date (MM/YY)</p> <p>MM/YY</p>	<p>* Security Code (3-digit number)</p> <p>Security Code</p>

Previous
Submit

Please note that after you click the Submit button, you cannot make changes to your application.

- You will get confirmation number if successful
 - If you entered any invalid information, you will see a message indicating that your card was invalid.



Click on Ok and reenter the correct information and click on Submit to complete the application.

If submission was successful, you will see a confirmation dialog box with a message indicating that your application was submitted successfully.

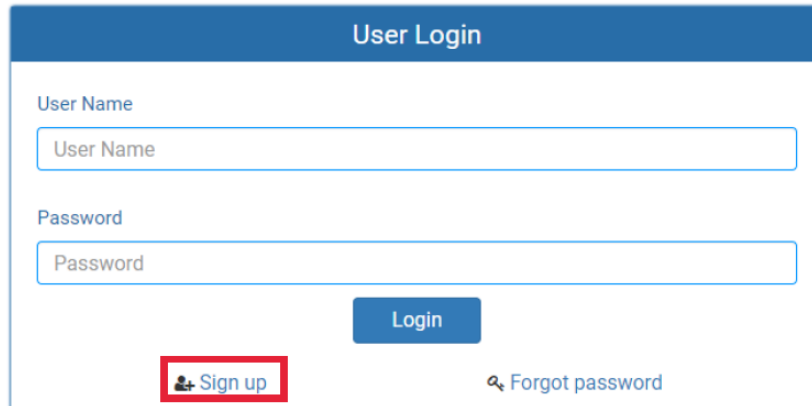
After your application has been submitted, the Board will:

- Review the application
- Email registrant if additional information is needed
- Approve or deny the application

After the new license has been approved/issued:

Once the new license is approved/issued, an Online Business Profile will need to be set up. This will allow the ability to print the facility license and produce a receipt, if desired. Click on this link to begin the process: (https://sdbop.igovsolution.com/online/User_login.aspx) Click on 'Sign up'.

ONLINE BUSINESS PROFILE LOGIN

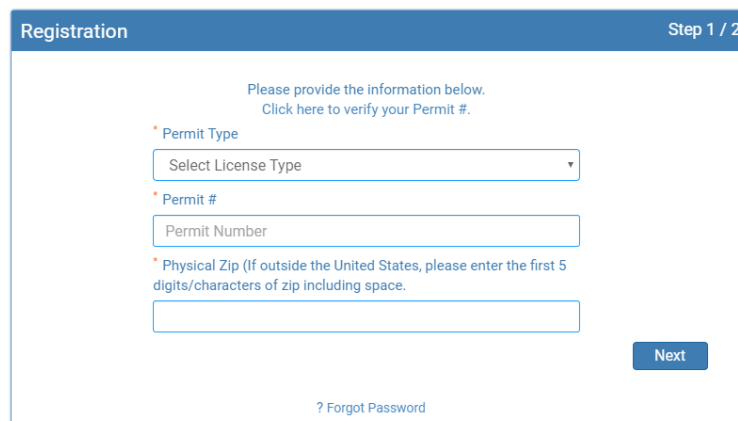


The 'User Login' form has a blue header with the title 'User Login'. It contains two input fields: 'User Name' and 'Password'. Below the 'Password' field is a blue 'Login' button. At the bottom left, there is a 'Sign up' button with a user icon, which is highlighted with a red rectangle. At the bottom right, there is a link for 'Forgot password' with a magnifying glass icon.

1. Sign up:

- a** Click on the Sign-up button in the User Login screen it will take you to the Registration page.

ONLINE BUSINESS PROFILE

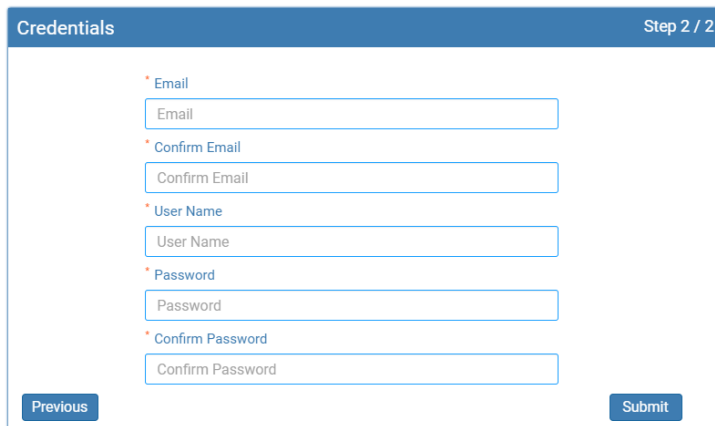


The 'Registration' form is titled 'Step 1 / 2'. It instructs the user to 'Please provide the information below.' and includes a link to 'Click here to verify your Permit #.'. The form contains three required fields: 'Permit Type' (a dropdown menu with 'Select License Type'), 'Permit #' (a text field with 'Permit Number'), and 'Physical Zip' (a text field with instructions: 'If outside the United States, please enter the first 5 digits/characters of zip including space.'). A blue 'Next' button is located at the bottom right. A link for '? Forgot Password' is at the bottom center.

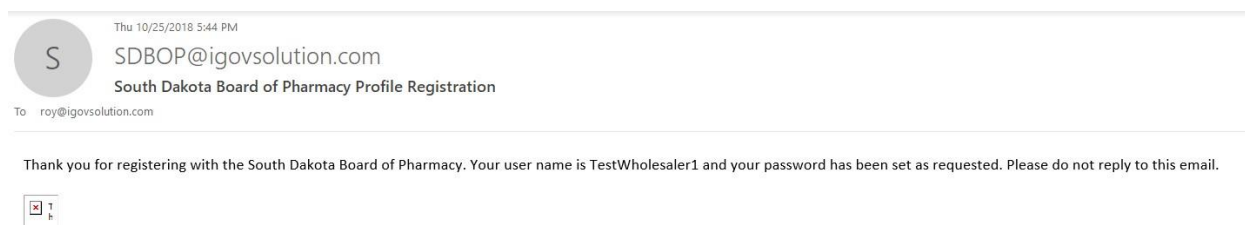
- b** Select the permit type from the drop down (in this case select Wholesale)
- c** Enter the Permit number (that is printed on your license. **Note:** Enter similar to 600-0000)
 - i** License number can be found on the verification page:
https://sdbop.igovsolution.com/online/Lookups/LookUp_Business.aspx
- d** Then enter the Physical zip of the location / business

- e Click Next and it will take you to the Step 2-- i.e. creating your login credentials, like shown below. Note: Please remember the details that you are entering here in this screen, the email that you are using to register, your user name, and password

ONLINE BUSINESS PROFILE



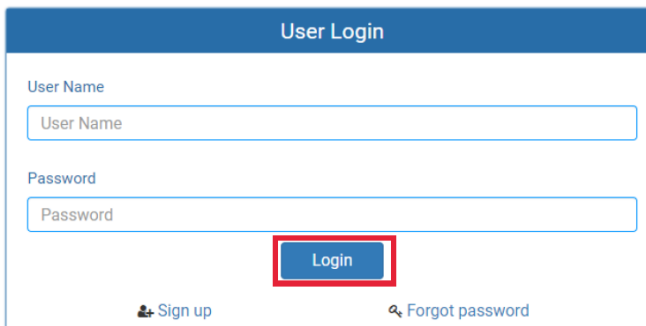
- f Once user registration is successful, an e-mail will be triggered to the e-mail that you provided during your registration with a similar message to what is shown below:



2. Profile Login:

- a. Use the user id and password to login in the Profile page and it will take you to the My Profile page as shown below (https://sdbop.igovsolution.com/online/User_login.aspx):

ONLINE BUSINESS PROFILE LOGIN



- b. To print the facility license, go to the Registration Information section, click on the blue 'Print' under the Certificate column.

Registration Information

Type	Licensor #	Issue Date	Exp Date	Status	Last Renewal Date	Renew	Certificate
Filters	Filters	Filters	Filters	Filters	Filters		
Wholesale	600-0000	10/30/2018	12/31/2018	Current/Active	10/30/2018	Renew	Print

- c. To print a receipt, go the section Payment History section, click on the small printer under the receipt column to the right for receipt desired.

Payment History

Receipt #	Payment Method	Date Received	Payer	Amount	Receipt
Filters	Filters	Filters	Filters	Filters	
20190430000002887	Credit Card	04/30/2019	0000	\$200.00	